

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,322	01/02/2004	Timothy Joseph Johnson	CRNI.110509	4676
46169 SHOOK HAR	7590 02/12/2007 PDV & BACON LLP		EXAMINER	
SHOOK, HARDY & BACON L.L.P. Intellectual Property Department			NGUYEN, TRAN N	
	BOULEVARD Y, MO 64108-2613		ART UNIT	PAPER NUMBER
			3626	-
SHORTENED STATUTO	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		02/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
	10/750,322	JOHNSON, TIMOTHY JOSEPH				
Office Action Summary	Examiner	Art Unit				
	Tran N. Nguyen	3626				
The MAILING DATE of this communication appeariod for Reply	ppears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING I  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO .136(a). In no event, however, may a reply be t d will apply and will expire SIX (6) MONTHS fror tte, cause the application to become ABANDON	N. imely filed  In the mailing date of this communication.  ED (35 U.S.C. § 133).				
Status		·				
1) Responsive to communication(s) filed on 02.	January 2004.					
	is action is non-final.	·				
3) Since this application is in condition for allow	· ·	osecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-33 is/are pending in the application.						
4a) Of the above claim(s) is/are withdra	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-33</u> is/are rejected.						
7) Claim(s) is/are objected to.	')☐ Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/	or election requirement.	•				
Application Papers		•				
9)⊠ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>02 January 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a lis	st of the centified copies not receiv	ea.				
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)		4) Interview Summary (PTO-413) Paper No(s)/Mail Date.				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal 6) Other:					

#### **DETAILED ACTION**

#### Notice to Applicant

This communication is in response to the application filed 02 January
 Claims 1-33 are pending. An IDS has not been entered or considered in this case.

#### Abstract

- 2. The abstract of the disclosure is objected to for the following reasons: the abstract exceeds 150 words in length.
- 3. Correction is requested. See MPEP § 608.01(b).

## Claim Objections

4. Claims 3, 14, and 25 are objected to because they recite the limitation "*Medicare* guidelines and *Medicare* guidelines". Examiner anticipates that Applicant is intending to recite Medicare and *Medicaid* guidelines, and has examined these claims to recite as such.

Appropriate correction is requested.

# Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 6. Claims 23-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
- (A) As per claim 23, Applicant recites "a clinically related billing item" (line 1) being generated according to the recited method. This is a product-by-process claim; however, the recited method steps do not generate a billing item. The first method step recites that the billing item is received, while the second step recites that the billing item is verified. None of these two steps generates a billing item. Thus, the final product as recited in the preamble is not generated by the recited method.

Therefore, based upon Applicant's disclosure, one of ordinary skill in the art would not know how to make and use the invention as claimed by Applicant.

(B) All claims dependent thereon, namely claims 24-33, fail to remedy these deficiencies, and are rejected for the same rationale as applied to the rejection of claim 23.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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- 8. Claims 1-11, 14, 23-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are replete with errors, as discussed below.
- (A) Claim 1, line 4, "the unique billing item" (line 4) lacks proper antecedent basis. For purposes of applying prior art, "the unique billing item" is interpreted as any received "billing item".
- (B) All claims dependent thereon, namely claims 2-11, fail to remedy these deficiencies, and are rejected for at least the same rationale as applied to the rejection of claim 1.
- (C) Claim 2, line 1, "the mandatory billing guidelines" lack proper antecedent basis because no mandatory billing guidelines have been previously introduced in the scope of claim 2 or parent claim 1. For purposes of applying prior art, "the mandatory billing guidelines" is interpreted to as criteria used to verify claims.
- (D) All claims dependent thereon, namely claim 3, fail to remedy these deficiencies, and are rejected for at least the same rationale as applied to the rejection of claim 2.

(E) Claim 3, line 3, "Medicare guidelines and Medicare guidelines" renders the scope of the claim indefinite because Applicant has not positively recited the legal requirements with which the guidelines are compliant. Additionally, since legal requirements change as time progresses, the aforementioned limitation is considered relative terminology and the scope of the claim cannot be fully ascertained by one of ordinary skill in the art. Specifically, it is unclear which law and which version of that law Applicant is reciting. Furthermore, Applicant has not recited specific limitations that would render the guidelines compliant with law.

Additionally, parent claim 2 recites the limitation "the mandatory billing guidelines comprise at least one of regulatory and administrative guidelines" (lines 1-2). Claim 3 further recites the limitation "the mandatory billing guidelines comprise at least regulatory guidelines" (lines 1-2). Claim 3's recitation renders the scope of claim 3 indefinite because it is ambiguous if Applicant intends the scope of claim 3 to encompass the administrative guidelines.

For purposes of applying prior art, Examiner interprets claim 3 to recite that mandatory guidelines are comprised of regulatory guidelines, and may optionally be comprised of administrative guidelines. The regulatory guidelines are comprised of any requirements as set forth by any version of Medicare/Medicaid regulations.

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(F) Claim 14, line 2, "Medicare guidelines and Medicare guidelines" exhibit the

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same issues as discussed in the rejection of claim 3.

(G) Claim 23 recites a method of generating a billing item; however, the

method steps do not generate a billing item, as discussed in the section above.

The scope of this claim is indefinite because it is ambiguous if Applicant is

reciting a product-by-process claim, or if Applicant is intending to recite a method

of using the billing item.

Furthermore, claim 23 is incomplete for omitting essential steps, such

omission amounting to a gap between the steps. See MPEP § 2172.01. The

omitted steps are the method steps necessary to generate the billing item as

recited in the preamble.

(H) All claims dependent thereon, namely claims 24-33, fail to remedy these

deficiencies, and are rejected for at least the same rationale as applied to the

rejection of claim 23. Furthermore, these claims exhibit substantially the same

errors as discussed in the rejections of claims 1-11.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent

therefor, subject to the conditions and requirements of this title.

- 10. Claims 23-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
- (A) As per claim 23, this claims recites a "clinically related billing item". Based upon Applicant's disclosure and Figure 1, Examiner interprets this limitation to recite a data item, i.e. a data structure with a list of data elements. Data items are non-functional descriptive materials in that they impart no functionality even when stored on a computer-readable medium because the non-functional descriptive materials contain no computer instructions.

As disclosed by Applicant, a "clinically related billing item" is not a process, machine, manufacture, or composition of matter. Therefore, this claim is directed towards nonstatutory subject matter. As such, non-functional descriptive materials are ineligible for patent protection under 35 U.S.C. 101.

(B) All claims dependent thereon, namely claims 24-33, fail to remedy these deficiencies, and are rejected for at least the same rationale as applied to the rejection of claim 23.

For purposes of applying prior art, Examiner interprets these claims to recite a method of using a billing item.

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### Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35U.S.C. 102 that form the basis for the rejections under this section made in thisOffice action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 12. Claims 1-2, 4-7, 9-12, 15-18, 20-23, 26-29, 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Holloway et al. (5,253,164).
- (A) As per claim 1, Holloway discloses a medical claims processing system(Abstract) comprising:
- (a) a user interface for inputting medical claims information (col. 4 lines 25-33, Fig. 1 label 2) (It is noted that any system capable of accepting inputs will have an "input interface". This is the interface by which the system is able to accept inputs. Even if not explicitly taught, the point of entry for input data is the de facto "input interface"); and
- (b) software means for performing claims verification (col. 4 lines 54-64, Fig. 1, labels 5-6, Fig. 2-7) (It is noted that an expert system with software means is considered "a conditioning engine").
- (B) As per claim 2, Holloway discloses that claims containing overlapping medical procedures are screened to prevent double payment (col. 3 lines 38-68)

(It is noted that guidelines as set forth by the insurance provider is a form of "administrative guidelines").

- (C) As per claim 4, Holloway discloses a table of rules for claims verification (col. 4 lines 14-15, Fig. 6, Appendix B) (It is noted that a listing of data elements to be verified against claim information is considered "a compliance template").
- (D) As per claim 5, Holloway discloses that criteria such as "age of the patient, claim number, date(s) of treatment(s) and procedure(s), the name of the physician, etc." as well as CPT-4 diagnostic codes may be considered by the system (col. 4 lines 28-33, col. 3, lines 38-68).
- (E) As per claim 6, Holloway discloses that invalid claims are "pended" for further review (col. 10 lines 8-16, Fig. 2) (It is noted that holding claims in a waiting area for further review is a form of "a holds queue").
- (F) As per claim 7, Holloway discloses that invalid claims are further reviewed (col. 10 lines 8-16) (It is noted that since additional information is needed to "aid in processing the claims", it is anticipated that the claim will be further reviewed when additional information becomes available).
- (G) As per claim 9, Holloway discloses that the user obtains information from the physician or the billing entity (col. 10 lines 8-16) (It is noted that because user

3 is a person, and because Holloway teaches that user 3 obtains additional information, it is anticipated that user 3 performs a manual search for additional clinical documentation. It is also noted that "manual" means not automated, i.e. performed by human beings, and that "documentation" may be information in any format).

- (H) As per claim 10, Holloway discloses that knowledge base 6 is comprised of a plurality of individual database elements that hold the various information used in verification (col. 4 lines 35-40, Fig. 2 labels 17, 27, 34, 40, Fig. 3 labels 11, 12, 17, Fig. 4-5).
- (I) As per claim 11, Holloway discloses that knowledge base 6 is updatable via history database 7 (col. 4 lines 68, col. 5, lines 1-3) (It is noted that Examiner interprets the limitation "database" to recite a data storage sorted for retrieval).
- (J) Claims 12, 15-18, and 20-22 repeat the limitations of claims 1, 4-7, and 9-11, respectively, and are therefore rejected for the same reasons as claims 1, 4-7, and 9-11, and incorporated herein.
- (K) Claims 23, 26-29, and 31-33 repeat the limitations of claims 1, 4-7, and 9-11, respectively, and therefore rejected for the same reasons as claims 1, 4-7, and 9-11, and incorporated herein.

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## Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 15. Claims 3, 13-14, 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holloway et al. (5,253,164), as applied to the rejections of claims 1, 12, 23.
- (A) As per claim 3, Holloway does not explicitly disclose that billing guidelines are comprised of Medicaid/Medicare guidelines; however, Holloway teaches that physician incentives resulting from upcoding are driving changes to the Medicare/Medicaid fee-payment structure (col. 1 lines 39-65). Holloway also recognizes that there exists a need to detect and correct errors arising from

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Medicare/Medicaid claims as the result of this upcoding (column 1, lines 66-68 and column 2, lines 1-16).

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to verify claims against Medicare/Medicaid guidelines when implementing the system of Holloway with the motivation of saving expenses while maintaining productivity (col. 2 line 68, col. 3 lines 1-5) and paying only appropriately coded claims amounts (col. 3 lines 6-11).

- (B) Claims 13-14 repeat the limitations of claim 3, and are therefore rejected for the same reasons as claim 3, and incorporated herein.
- (C) Claims 24-25 repeat the limitations of claim 3, and are therefore rejected for the same reasons as claim 3, and incorporated herein.
- 16. Claims 8, 19, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holloway et al. (5,253,164), as applied to claims 1, 6, 7, 12, 17, 18, 23, 28, 29, in view of Miller (5,235,702).
- (A) As per claim 8, Holloway does not explicitly disclose an automated search for additional clinical documentation.

Miller discloses an automated method by which medical records may be converted into electronic format (Abstract, Fig. 3).

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Because Holloway discloses that "in addition to the entries for the one or more medical procedures for which payment is sought, **other data such as** age of the patient, claim number, date(s) of treatment(s) and procedure(s), the name of the physician, **etc.**", as discussed in the rejection of claim 5, Holloway suggests that other information may be inputted into the system for verification.

Holloway further discloses that it is possible for "the development of new rules and a growth and refinement of the knowledge base interpreter 5" (column 10, lines 51-64). Therefore, it is clearly anticipated that Holloway intends for the expert system to grow and adapt to new rules.

Therefore, absent any evidence of criticality, the expert system as taught by Holloway may be adapted to integrate new rules, i.e. Medicare/Medicaid rules, into the expert system with no unexpected results.

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the features of Miller to provide electronic patient record for automated searches for additional clinical documentation to further review pending claims in the system of Holloway with the motivation of further reviewing claims, as discussed in the rejection of claim 7, in an efficient manner (Holloway; col. 2 lines 58-63).

(B) Claim 19 repeats the limitations of claim 8, and is therefore rejected for the same reasons as claim 8, and incorporated herein.

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(C) Claim 30 repeats the limitations of claim 8, and is therefore rejected for the same reasons as claim 8, and incorporated herein.

### Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches that insurance claims are automatically validated (4,491,725), a claims adjudication system (4,858,121), and a system that provides automatic verification of patient eligibility for claims processing (4,916, 611).

Any inquiry concerning this communication or earlier communications from Examiner should be directed to Tran N. Nguyen (Ken) whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 8:00 am - 5:00 pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, Examiner's Supervisor, Joseph Thomas can be reached on (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pairdirect.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (tollfree). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

### Any response to this action should be mailed to:

Commissioner of Patents and Trademarks Washington, D.C. 20231

## Or faxed to:

(571) 273 - 8000[Official communications]

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(571) 273 - 6767[Informal/Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

Tran N Nguyen Examiner

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TN

1/25/2007

Carolin Bleck Palent Examiner 3626 2/2/07